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JC976 U.S. PTO
09/818812
03/27/01

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03/27/01

PATENT

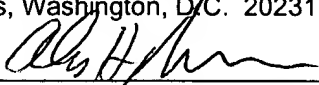
Date March 27, 2001

Docket No. 16743-7430

CERTIFICATION UNDER 37 CFR 1.10

I hereby certify that this New Application Transmittal and the documents referred to as enclosed therein are being deposited with the United States Postal Service on March 27, 2001 in an envelope as "Express Mail Post Office to Addressee" Mailing Label Number EL667240769US addressed to: Box Patent Application, Assistant Commissioner of Patents, Washington, D.C. 20231.

Alan H. Norman
(Type name of person mailing paper)


(Signature of person mailing paper)

NOTE: Each paper or fee referred to as enclosed herein has the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 CFR 1.10(b).

Box Patent Application
Assistant Commissioner of Patents
Washington, D.C. 20231

NEW APPLICATION TRANSMITTAL

Transmitted herewith for filing is the patent application of

Inventor(s): Roger Khouri, M.D.

For: METHOD AND APPARATUS FOR SOFT TISSUE ENHANCEMENT

Enclosed are:

1. Benefit of Prior U.S. Application (35 USC 120)

 X The new application being transmitted claims the benefit of a prior U.S. application and enclosed is added page for new application transmittal where benefit of a prior U.S. application claimed.

2. The Papers Required For Filing Under 37 CFR 1.53:

- 17 Pages of Specification
- 1 Pages of Abstract
- 4 Pages of Claims
- 6 Sheets of Drawing

 X formal informal

In addition to the above papers there is also attached:

- Pages of an Amendment
- X Return Receipt Postcard
- Information Disclosure Statement with copies of references.

09/818812 : 0322701

3. Declaration or oath

☒ Enclosed 3 pages
____ Newly executed (original or copy)
☒ Copy from a prior application (continuation/divisional with page 5 of 5 completed)
____ Deletion of Inventor(s) (signed statement attached deleting inventor(s) of prior application)
____ Not enclosed

4. Inventorship Statement

The inventorship for all the claims in this application are:

☒ the same

OR

____ are not the same and an explanation, including the ownership of the various claims at the time the last claimed invention was made, is submitted.

5. Language

☒ English ☐ Non-English

A verified English translation of the

[check applicable item(s)]

____ specification and claims

____ declaration

is attached.

6. Assignment

☒ An assignment of the invention to Bio-mecanica, Inc.

____ is filed under separate cover sheet

☒ was filed in the prior application

____ will follow

7. Certified Copy

____ (Country) (Application No.) (Filed)

from which priority is claimed

____ is attached

____ will follow

8. Fee Calculation

CLAIMS AS FILED

	Number Filed	Provided with Basic Fee	Number Extra	Rate	Basic Fee \$710
Total Claims	22	20	2	X \$18.00	\$ 36.00
Independent Claims	5	3	2	X \$80.00	\$ 160.00
Multiple Dependent Claim(s), if any	0	0	0	X \$270.00	\$.00

☐ Amendment canceling extra claims enclosed

☐ Amendment deleting multiple dependencies enclosed

☐ Fee for extra claims is not being paid at this time

Filing Fee Calculation

\$ 906.00

9. Small Entity Statement

☐ verified statement that this is a filing by a small entity under 37 CFR 1.9 and 1.27 is attached.

Filing Fee Calculation (50% of above)

\$ _____

10. Fee Payment Being Made At This Time

☒ Enclosed

☒ basic filing fee

\$ 906.00

Total fees enclosed

\$ 906.00

11. Method of Payment of Fees

☒ check in the amount of \$ 906.00

12. Authorization to Charge Additional Fees

 X The Commissioner is hereby authorized to charge the following additional fees which may be required to Account No. 18-1829;

 X 37 CFR 1.16 (filing fees and presentation of extra claims)

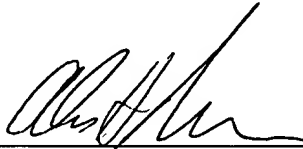
 X 37 CFR 1.17 (application processing fees)

 37 CFR 1.18 (issue fee at or before Mailing of Notice of Allowance, pursuant to 37 CFR 1.311(b)).

13. Instructions As To Overpayment

 X credit Account No. 18-1829

14. Correspondence Address



Alan H. Norman
Reg. No. 32,285
HOWELL & HAUSERKAMP, L.C.
7733 Forsyth Boulevard
Suite 1400
St. Louis, Missouri 63105
(314) 727-5188

FOI 2025-032704

15. Benefits of Prior U.S. Application

This application is a

- ☒ continuation
☐ continuation-in-part
☐ divisional

of co-pending U.S. Patent Application Serial No. 09/141,460 filed August 27, 1998,

of prior U.S. Patent Application Serial No. 09/141,460 filed August 27, 1998, which is a continuation of U.S. Patent Application Serial No. 08/698,941 filed August 16, 1996, which is a continuation-in-part of U.S. Patent Application Serial No. 08/516,623 filed August 18, 1995, (now U.S. Patent 5,676,634), which is a continuation-in-part of U.S. Patent Application Serial No. 08/504,640 filed July 20, 1995 (now U.S. Patent 5,695,445), which is a continuation of U.S. Patent Application Serial No. 08/220,186 filed March 30, 1994 (now U.S. Patent 5,536,233)

International Application ☐ filed

- ☒ Incorporation by Reference
The entire disclosure of the prior application, from which a copy of the oath or declaration is supplied under item 3., is considered as being part of the disclosure of the accompanying application and is hereby incorporated by reference therein.

16. Maintenance of Copendency of Prior Application

- ☐ A petition, fee and response has been filed to extend the term in the pending prior application until

17. Conditional Petition for Extension of Time in Parent Application

- ☐ A conditional petition for extension of time is being filed in the pending parent application.

18. Relate Back -- 35 U.S.C. 120

- ☐ Amend the specification by inserting before the first line the sentence:

This is a

- ☐ continuation
☐ continuation-in-part
☐ divisional
☐ provisional

of copending application

- ☐ Serial number ☐; filed on
☐ PCT International Application ☐; filed on

19. Abandonment of Prior Application (if applicable)

- ☐ Please abandon the prior application at a time while the prior application is pending or when the petition for extension of time in that application is granted and when this application is granted a filing date so as to make this application copending with said prior application.

PATENT

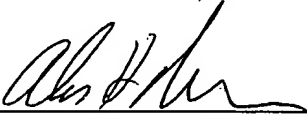
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

St. Louis, Missouri
March 27, 2001

CERTIFICATE OF EXPRESS MAILING UNDER 37 C.F.R. § 1.10

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Alan H. Norman
Type or Print Name


Signature

In re application of: :
Khoury, Roger K. :

Docket No.: 16743-7430 :

Filed: Herewith :

For: METHOD AND APPARATUS FOR :
SOFT TISSUE ENHANCEMENT :

BOX PATENT APPLICATION
Assistant Commissioner for Patents
Washington, D.C. 20231

NOTICE OF INTERFERING SUBJECT MATTER

Applicant's present application is a continuation of co-pending U.S. Patent Application Serial No. 09/141,460 filed August 27, 1998 entitled "Vacuum Dome With Supporting Rim And Rim Cushion," which is a continuation of U.S. Patent Application Serial No. 08/698,941 filed August 16, 1996 entitled "Vacuum Dome With Supporting Rim And Rim Cushion" (now abandoned), which is a continuation-in-part of U.S. Patent

Application Serial No. 08/516,623 filed August 18, 1995 entitled "Method And Apparatus For Soft Tissue Enlargement With Balanced Force Appliance" (now U.S. Patent 5,676,634), which is a continuation-in-part of U.S. Patent Application Serial No. 08/504,640 filed July 20, 1995 entitled "Method And Apparatus For Soft Tissue Enlargement By Distractive Force" (now U.S. Patent 5,695,445), which is a continuation of U.S. Patent Application Serial No. 08/220,186 filed March 30, 1994 entitled "Method And Apparatus For Soft Tissue Enlargement" (now U.S. Patent 5,536,233).

Kaiser U.S. Patent 6,042,537, issued March 28, 2000, based on application Serial No. 08/915,540, filed August 13, 1997. The effective filing date of the present application is earlier than that of the Kaiser patent. Many claims of the present application correspond exactly or substantially to claims of the Kaiser patent. In particular, claims 1-7 of the present application are identical to claims 1-7 of the Khouri patent, and claims 13-19 of the present application correspond exactly to claims 20-26 of the Khouri patent. Claim 8 of the present application corresponds substantially to claim 1 of the Kaiser patent. Claim 10 of the present application corresponds substantially to claim 7 of the Kaiser patent.

Claim 20 of the present application corresponds substantially to claims 1 and 20 of the Kaiser patent. Applicant submits that a suitable count for an interference involving the present application and the Kaiser patent would be identical to applicant's claim 20. All claims of the Kaiser patent correspond substantially to applicant's claim 20.

Claims 8-12 of the Kaiser patent are directed to the same invention as claim 7 of the Kaiser patent because claim 7 either alone or in combination with the

relevant prior art renders obvious claims 8-12. Kaiser's claims 13-19 are directed to the same patentable invention as Kaiser's claim 1 because claim 1 either alone in combination with the relevant prior art renders obvious claims 13-19. Kaiser's claims 27-31 are directed to the same patentable invention as Kaiser's claim 26 because claim 26 either alone or in combination with the relevant prior art renders obvious claims 27-31. Kaiser's claims 32-38 are directed to the same patentable invention as Kaiser's claim 20 because claim 20 either alone or in combination with the relevant prior art renders obvious claims 32-38.

The claim language of the present application is supported by the specification. Applicant's claim 1 (as well as Kaiser's claim 1) requires, *inter alia*, "a flexible mass affixed to the open end of said vessel to absorb the pressure exerted by said vacuum, thereby acting as a seal and force diffuser." The patent specification describes a flexible mass in the form of gasket 46 described as "a silicone gel cushion or other soft, conforming type material." Applicant's specification, ¶37. The purpose of the gasket is "to improve the patient's comfort and enhance the seal about the rim." Applicant's specification, ¶37. That the gasket 46 absorbs the pressure exerted by the vacuum and diffuses¹ or spreads the force created by the vacuum is made plain in the specification of the application where it explains (Applicant's specification, ¶34):


The contact pressure P_2 of the rim 14 against the user is equal to this opposing force F_2 divided by the annular rim surface area 34, A_2 , i.e., $P_2 = F_2 / A_2$ or $F_2 = P_2 A_2$. As the magnitude of the opposing force is equal to the magnitude of the formal force, $F_1 = F_2$ and $P_1 A_1 = P_2 A_2$. Therefore, if the rim surface area 34, A_2 is configured to be greater than or equal to the normal area 32, A_1 at the dome opening, then the contact pressure against the patient's skin will not exceed the magnitude of the vacuum within the dome 12, i.e., $P_2 = P_1$.

¹ A "diffuser" is "one that diffuses," and "diffuse" means "to break up and distribute . . . to spread out or become transmitted esp. by contact." *Webster's Seventh New Collegiate Dictionary*.

Thus, Applicant's specification makes it clear that the contact pressure of the rim against the user is decreased by increasing the surface area of the rim to which the gasket is affixed. By application of simple physics, the increased surface area spreads or diffuses the forces created by the vacuum. This is supported by the drawings which show the rim 14 and gasket 46 as having much greater surface areas than the edge of the vessel (dome 12). So it is clear that the gasket 46 is a flexible mass, is affixed to the open end of the vessel, absorbs the pressure exerted by the vacuum, and acts as both a seal and a force diffuser between the vessel and the tissue adjacent the periphery of the vessel.

Applicant's claim 6 requires the flexible mass to include an air pocket. Applicant's specification states that an inflated membrane or bladder could be employed. Applicant's specification, ¶¶40 and 44. An inflated membrane or bladder must include an air pocket. Thus, the specification supports the recitation of an air pocket.

Respectfully submitted,



Alan H. Norman
Reg. No. 32,285
Howell & Haferkamp, L.C.
7733 Forsyth Boulevard, Suite 1400
St. Louis, Missouri 63105
(314) 727-5188

March 27, 2001